B1 cont

trail batch size of the fluidized bed was 4 kg, twice the weight recommended for the 5 L Huttlin Turbojet processing container used, to ensure the fluidized material was close to the processing containers filter giving the best chance for the bacteria to escape through the 20 micron filter. The solid core (tablet granule core materials) comprised 66% w/w dextrose, 13% w/w gelatin, 15% w/w starch. The spraying liquid containing bacteria comprised either 1.16×10^{12} CFU *Lactobacilli*, or 3.5×10^{12} CFU *Lactobacilli/Bifidus*, with 3% w/w mannitol, 1% w/w egg albumin, 1% w/w glycerol, 1% w/w sodium phosphate buffers and made up to 1000 ml with purified water. --.

Page 35, lines 40-43, delete in their entirety, and insert therefor

B2

-- Enteric Coating Solution

Cellulose Acetate Phthalate	0.16kg
Sodium Hydroxide qs to pH 6	
Purified water to 8 kg of total batch size --.	

Page 43, lines 7-16, delete in their entirety, and insert therefor

B3

-- Coating Liquid

Interferon α 2b 40 billion IU	
Mannitol	0.200kg
Propylene glycol	0.075kg
Gelatin (succinylated)	0.025kg
Glycine	0.012kg
Egg Albumin	0.001kg
Standard sodium phosphate buffers to pH 7	0.073kg
Water for injection to	2.000kg --.

Page 43, lines 24-27, delete in their entirety, and insert therefor

B4

-- 1 Inferon α, glycine, mannitol, gelatin succinylated, propylene glycol, and buffers are dissolved in water for

B4cont

injection then filtered through 0.22 micron membrane filter. Albumin was added and made up to weight with water for injection. --.

Page 44, lines 16-24, delete in their entirety, and insert therefor

B5

-- Coating Liquid

Interferon α 2b 40 billion IU	
Mannitol	0.200kg
Propylene glycol	0.150kg
Gelatin (succinylated)	0.050kg
Glycine	0.012kg
Egg Albumin	0.001kg
Standard sodium phosphate buffers to pH 7	0.073kg
Water for injection to	2.000kg --.

Page 46, lines 21-31, delete in their entirety, and insert therefor

-- Coating Liquid

B6

Interferon α 2b 40 billion IU	
Mannitol	0.200kg
Propylene glycol	0.150kg
Gelatin (succinylated)	0.500kg
Glycine	0.120kg
Egg Albumin	0.020kg
Ascorbic Acid	0.057kg
Standard sodium phosphate buffers to pH 7	0.073kg
Water for injection to	4.000kg --

Page 50, lines 32-38, delete in their entirety.

Page 51, lines 1-2, delete in their entirety, and insert therefor

-- Coating Liquid

Interferon α 2b 40 billion IU	
Mannitol	0.200kg
Propylene glycol	0.150kg
Gelatin (succinylated)	0.050kg
Glycine	0.012kg
Egg Albumin	0.001kg
Standard sodium phosphate buffer to pH 7	0.073kg
Water for injection to	2.000kg --

B7

Page 54, Table 12, delete in its entirety, and insert therefor

-- **Table 12**

B8

	% w/w
Povidone BP/Eur.P	0.10
Disodium edetate BP/Eur.P	0.14
Polysorbate 80 BP/Eur.P	0.20
Dextran 45,000 BP/Eur.P	0.22
Sodium dihydrogen phosphate BP/Eur.P (Anhydrous Weight)	0.27
Disodium hydrogen phosphate BP/Eur.P (Anhydrous Weight)	0.58
Glycine BP/Eur.P	0.10
Sodium propyl hydroxybenzoate BP/Eur.P	0.03
Sodium methyl hydroxybenzoate BP/Eur.P	0.09
Albumin BPC	0.05
TOTAL	1.78
Purified water BP/Eur.P to	100% --

Page 55, the Table, delete in its entirety, and insert therefor

B9

-- **Hydrogel Core**	% w/w
Dextrose (anhydrous) BP	46.52
Starch BP (anhydrous wt)	20.00
Gelatin BP/Eur.P (anhydrous wt)	20.00
Carmellose BP (anhydrous wt)	2.00
Coating Liquid	
EPO (Epoetin Alfa) 250,00 IU	
Dextran 40,000 BP/Eur.P	0.600
Sodium Dihydrogen Phosphate BP/Eur.P	0.042
Disodium Hydrogen Phosphate BP/Eur.P (anhydrous wt)	0.057
Glycine BP/Eur.P	0.030
Trehalose	0.600
Sodium Edetate BP	0.025
Propylene Glycol BP	0.050
Egg Albumin	5.030
Sodium Chloride BP	0.046
Leucine USP	3.000
TOTAL	98%
Purified Water BP/Eur.P to	100% --

Page 55, lines 4-7, delete in their entirety, and insert therefor

B10

--1 EPO, dextran, glycine, trehalose, sodium edetate, propylene glycol, sodium chloride, leucine and buffers were dissolved in purified water then albumin was added and made up to weight with purified water. --.

Page 58, lines 31-34, delete in their entirety.

Page 59, lines 1-10, delete in their entirety, and insert therefor

B11

-- Finally, it is contemplated by the inventors of the present invention that the novel process described herein may be used to prepare other materials and to manipulate materials to particular ends. In particular, it is envisaged that the inventive process may be manipulated to allow for enteric

Bl cont

coating of microcapsules using solvents or aqueous methods such as sodium salts of cellulose acetate phthalate, to create sustained release properties by changing the core material polymers to a higher molecular weight or by using a combination of hydrogel core such as high molecular weight gelatin, polyvinyl pyrrolidone, alginates, carboxymethyl cellulose, various cellulose derivative, polyethylene glycols, albumin, dextran, carrageenan (one of ordinary skill in the art of formulation will be able to provide various combinations to create a desired release profile), create time release properties by varying the nature of polymers used and the thickness of the coatings and to allow for microdistribution of trace materials among large amount of solid mass. --.

REMARKS

The amendments to the specification has been made in order to correct clerical errors and inconsistencies therein. Hence, the amendments to the specification does not constitute new matter, and thus entry is respectfully requested.

The Examiner is invited to contact the undersigned at the below-listed number on any questions which might arise.

Respectfully submitted,

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